

Minutes and Actions for Biologics Subteam Discussion (March 19, 2009)

WIKI Link: <http://spl-work-group.wikispaces.com/Biologics>

Minutes:

Training Opportunities [<http://spl-work-group.wikispaces.com/Training>]

UNII Codes for CBER Active Ingredients

- Sponsor communications containing UNII codes for currently active products still being mailed. Check the letter carefully, as some sponsors have received letters with active ingredients missing, or misclassified. Before submitting a formal response, check with the signer of the letter. They may provide a revised letter, and save you from a formal submission.
- Alert your regulatory representation to be 'on the lookout' for letters, as they may not realize that the UNII codes are needed for SPL files.
- UNII code letters still seem to be limited to vaccine active ingredients.

Training Opportunities

- FDA is holding a second Face-to-Face for R4 training on June 10, 2009. Please contact the FDA at spl@fda.hhs.gov if you are interested in attending. The content at this June meeting should be very similar to that already being presented on May 21, 2009.

[REMINDER] Submission of SPL Content of Labeling

- For the first 12 months of CBER content-of-labeling SPL submission: include SPL with Annual Report – even if there have not been changes. This will result in all relevant products having SPL on file at the FDA within one year after implementation. Consult your Reviewer if there may be a delay in submitting an SPL.
- Draft SPL will be reviewed whether or not it has all UNII codes. If the codes are available, fill them in, as this facilitates the review process.
- Final SPL will not pass validation without UNII codes. It will not be posted on the DailyMed site without them.
- For eCTD submissions, SPL is placed in Module 1, section 14 (Labeling) in Draft Labeling or Final Labeling as appropriate.
- For other electronic submissions, make sure that the SPL content of labeling files are in their own \SPL folder. This folder must contain the *.xml file and any accompanying figures.
- Drug Listing and Establishment Registration SPL is required starting June 1, 2009. Prior to that, sponsors are being encouraged to submit these SPL through the eList Pilot Program.

Actions:

All Sponsor Reps:

If you are submitting SPL with upcoming CBER submissions for new, not-yet-approved products, and need UNII codes for your ingredients, alert the Review Division that UNII assignments are needed for one or more active ingredients and moieties.

Sponsor Reps with Immune Globulin products:

Continue to identify how your product(s) would be characterized.

Next Meeting: April 30, 2009.